

a control unit electrically coupled to the at least one pump for adjusting the volumetric ratio of the blood specimen to the at least one lysing agent in correspondence with an operator input;

a mixing chamber coupled in fluid communication with the at least one pump for receiving the pumped volumes of the respective blood specimen and the at least one lysing agent and creating a reagent mixture therefrom having a blood to lysing agent volumetric ratio corresponding to the operator input, and thereby creating a plurality of different reagent mixtures having a plurality of blood to lysing agent volumetric ratios corresponding to a plurality of different operator inputs; and

a sensing unit defining at least one counting orifice for receiving a reagent mixture and analyzing a particle distribution of the reagent mixture.

39. (New) An apparatus as defined in claim 38, wherein:

the operator input is indicative of one of a plurality of species;

the blood specimen corresponds to the indicated species; and

the reagent mixture has a blood to lysing agent volumetric ratio corresponding to the indicated species, and a plurality of different reagent mixtures having a plurality of blood to lysing agent volumetric ratios correspond to a plurality of different species.

Remarks

Claims 27 and 35 have been amended and new claims 36-39 have been added. Therefore, claims 27-39 are now pending in this application. In view of the above

amendments and the following remarks, it is respectfully submitted that these claims are allowable.

Claims 27-35 stand rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements. Claims 27-35 stand rejected under 35 U.S.C. § 103 as being unpatentable over Yamamoto or Collect Hematology in view of Kabata, Taylor, Dixon and Callan or Weiser. In addition, claim 35 stands rejected under the judicially created doctrine of obviousness-type double patenting. The Examiner's grounds for rejection are hereinafter traversed and reconsideration is respectfully requested.

Claim 35 stands rejected under the judicially-created doctrine of obviousness-type double patenting in view of Applicant's prior U.S. Patent No. 5,728,351. Accordingly, Applicant will submit an appropriate terminal disclaimer upon receiving an indication of allowable subject matter.

Claims 27-35 stand rejected under 35 U.S.C. § 112, second paragraph, due to the recitation of "a plurality of lysing agents." It is respectfully submitted that in view of the above amendments, including the deletion of the objectionable language, that this ground for rejection has been overcome.

Claims 27-35 stand rejected under 35 U.S.C. § 103 as being unpatentable over Yamamoto in view of Kabata, Taylor, Dixon and Callan or Weiser, and further stand rejected under 35 U.S.C. § 103 as being unpatentable over Collect Hematology in view of Kabata, Taylor, Dixon and Callan or Weiser. The Examiner's grounds for rejection are hereinafter traversed, and reconsideration is respectfully requested, particularly in view of the clarifying amendments to the claims.

Neither Yamamoto nor Collect Hematology teach or suggest an apparatus comprising a control unit or like means for adjusting a reagent mixture volumetric ratio of lysing agent to blood in correspondence with an operator input, as recited in the present claims. Rather, both Yamamoto and Collect Hematology teach systems that are fixed to make the same dilution ratios, with the same volumes of reagent-mixture components for every

blood sample. Kabata likewise does not teach or suggest adjusting or modifying the reagent mixture to correspond to an operator input, as recited in amended independent claims 27 and 35. Kabata's suggestion to adapt the commercially-available software for human blood so that it may be better used for research purposes in connection with animal blood concerns changing the histogram thresholds to accommodate animal (rabbit), as opposed to human cell types. The thresholds divide the cell populations on the histograms, and they cannot be changed on the systems identified (see, for example, Figure 2 of Kabata showing the thresholds in solid lines). Accordingly, Kabata suggests that the software might be adapted for research purposes to adjust the histogram thresholds to better accommodate the animal cell types tested. The "Technicon H1" software identified by Kabata similarly modified the histogram thresholds for rats and dogs, but did not require different reagent mixtures for the different species. Accordingly, Kabata makes no teaching or suggestion of adjusting or creating different reagent mixtures in response to different operator inputs, as recited in amended independent claims 27 and 35, and thus Kabata does not teach or suggest modification of either Yamamoto or Collect Hematology to achieve this purpose.

Taylor discusses various staining techniques for flow cytometry, but does not suggest adjusting or creating different reagent mixtures. Accordingly, Taylor does not materially add to the teachings of Yamamoto, Collect Hematology and Kabata with respect to the present invention.

Dixon et al. show experimental results with non-standard concentrations of the lysing agent Zapoglobin on canine leucocytes. Their results show that Zapoglobin concentrations of four times the standard concentration do not cause significantly increased lysis in that application. Therefore, the Dixon reference teaches away from using different concentrations of lysing agent to produce lysis in blood samples of different species, and does not materially add to the teachings of Yamamoto, Collect Hematology, Kabata and Taylor with respect to the present invention.

Callen et al. show evaluation of a system for hemoglobin measurement in dogs, cats, horses, and cows. Although their results summarize test result range differentials between those species, the Callen reference does not suggest alteration of the testing process for different species. Callen does not suggest changing the ratio of lysing agent to blood for different species, and may teach away from doing so by showing acceptable results obtained without regard to species during the actual testing. Therefore, Callen does not materially add to the teachings of Yamamoto, Collect Hematology, Kabata, Taylor and Dixon with respect to the present invention.

Weiser discusses various hematological techniques for different species, but does not suggest adjusting or creating different reagent mixtures. Weiser shows alteration of a device aperture current in order to count particles of sizes specific to common veterinary subjects. Weiser also shows doubling of the dilution ratio where the particles are too numerous to be counted accurately by the subject device. Weiser does not make any suggestion to adjust the volumetric ratio of lysing agent to blood according to the subject species. Accordingly, Weiser does not materially add to the teachings of Yamamoto, Collect Hematology, Kabata, Taylor, Dixon and Callen with respect to the present invention.

It is therefore respectfully submitted that amended independent claims 27 and 35, as well as new independent claim 38, are unobvious over either Yamamoto or Collect Hematology in view of Kabata, Taylor, Dixon and Callan or Weiser, for at least these reasons. Because claims 28-34, 36-37, and 39 each depend from one of these independent claims, it is respectfully submitted that these claims are likewise unobvious over the prior art references of record for at least the same reasons.

Accordingly, it is respectfully submitted that claims 27-39 are allowable, and an early action to that effect is earnestly solicited.

No fees in addition to the payment submitted herewith are believed to be required; however, if an additional fee is required, or to cover any deficiency in fees already paid, authorization is hereby given to charge our deposit account no. 11-0231.

Respectfully submitted,

By *Eric Parham*
Eric M. Parham (Reg. No. P-45,747)
Mark D. Giarratana (Reg. No. 32,615)
Attorneys for Applicant